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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/468,496	12/21/1999	RON WAKSMAN M. D.	WELD-111-DIV	3711

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EXAMINER

DESANTO, MATTHEW F

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/468,496

Applicant(s)WAKSMAN M. D. ET AL. *On***Examiner**

Matthew F DeSanto

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/23/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-35, 37, 42-44 and 47-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-35, 37, 42-44, 47-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/17/04, 9/28/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 29-35, 37, 42, and 44 are rejected under 35 U.S.C. 102(e) as being anticipated by Weaver et al. (USPN 5, 843, 028).

Weaver et al. discloses a catheter comprising, a first tube having a lumen closed at its distal end and sized to receive the treating element, a second tube in parallel relation to the first tube and having a lumen open at its distal end and sized to receive a guidewire, and a third tube for receiving first and second tube and having a fluid return lumen in fluid communication with the lumen of the first elongated tube.

Where the distal end of the third tube (as shown in figure 23) extends beyond the distal ends of the first and second tubes. Wherein the distal end of the second tube is coterminous with the distal end of the third tube, both which extend beyond the distal end of the first tube. Wherein the lumen of the first tube has an inside diameter less than twice the outside diameter of the treating element. Wherein the first tube includes

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an internal barrier to block the passage of the treating element out of the first tube, and where the internal barrier has an aperture (Figures 6, 13B, 23 and entire reference).

3. Claims 29, 32-34, 42, 43, 44, and 47 are rejected under 35 U.S.C. 102(e) as being anticipated by Harrison et al. (USPN 5,554,119).

Harrison et al. discloses a catheter comprising, a first tube (172) having a lumen partially closed at its distal end and sized to receive the treating element, a second tube (32) in parallel relation to the first tube and having a lumen open at its distal end and sized to receive a guidewire, and a third tube (164) for receiving first and second tube and having a fluid return lumen in fluid communication with the lumen of the first elongated tube. (Figure 3B, and entire reference)

Wherein the lumen of the first tube has an inside diameter less than twice the outside diameter of the treating element. Wherein the first tube includes an internal barrier to block the passage of the treating element out of the first tube, and where the internal barrier has an aperture. (Figure 3B and entire reference).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 29-35, 37, 42-44, 47-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harrison et al. (USPN 5,554,119) as applied above.

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At the time of the invention it would have been obvious for one of ordinary skill in the art to modify the invention with regards to the catheter length and shape. It is well known in the catheter and tubing art to modify the length and the diameter (size) of catheters as well as the shape of the catheter. Claims 30, 32, 35, 37 are all routine modification that are well known in the catheter and tubing art. The examiner would also like to state that it would have been an obvious matter of design choice to one skilled in the art to modify the apparatus as taught by Harrison et al. to have the distal end of the catheter as claimed, since applicant has not disclosed any criticality, novelty and/or unexpected results and it appears that the invention would perform equally well with any distal end catheter structure, such as the catheter as taught by Harrison et al.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 29-34, 35, 37, 42, 43, 44, 47, 48, and 49 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11, 12, 17, 19, 20, 22, 35, of U. S. Patent No. 5,899,882. Although the

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conflicting claims are not identical, they are not patentably distinct from each other because the patent and the application are claiming common subject matter, as follows: a first, second and third tube with a treating element placed in one of the tubes and the only variation is an obvious modification, which is the reinforcing connector. The application has the same principle, but never positive recites the reinforcing connector.

Allowable Subject Matter

8. Claims 48 and 49 are in conditions for allowance over the prior art, but must still overcome the double-patented rejection.

Response to Arguments

9. Applicant's arguments, with respect to Nita has have been fully considered and are persuasive. The 102 rejection of Nita has been withdrawn.

10. Applicant's arguments filed 9/23/04 have been fully considered but they are not persuasive with regards to Harrison et al.

11. The applicant argues with respect to Harrison et al. functional language of the first and third lumen. With regard to the first lumen, there is no structure and no dimensions given to the treating element. The first lumen of the prior art would be capable of allowing a treating element to pass through, since the definition of a treating element is very broad. The third lumen encompasses the first and second lumen, and therefore would be able to perform the function of acting as a return lumen, since there is a proximal port as shown in figure 15 and 16.

12. The examiner would also like point out MPEP section 2114, because the applicant is replying on functional language to overcome the prior art instead of

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structure. This section of the MPEP states that there must be distinguishing structure in order to allow a case and find patentable subject matter.

13. With regards to the double patenting rejection, the examiner understands that there are certain limitations in the U. S. Patent No. 5,899,882 that are different in the patented claims, but these limitations are obvious modifications with regards to the medical art. Therefore, the double patenting is of the obvious type. The examiner can provide a secondary reference to show level of skill in the art in the medical art. It is well known to make catheters with a balloon or without within the same patent.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F DeSanto whose telephone number is 1-703-305-3292. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick LUCCHESI can be reached on (703) 308-2698. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.


NICHOLAS D. LUCCHESI
SUPERVISOR PATENT EXAMINER
TECHNOLOGY CENTER 3700

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Matthew DeSanto
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December 13, 2004